





line 15 of the application, *Tetrahymena pyriformis* bioencapsulates *Bacillus* spores, and hence concentrates and aids in the detection of *Bacillus* species (e.g. *Bacillus anthracis*).

Claim 17-21 and 29-36 stand rejected as indefinite. The Examiner states that there is no active process step that uses the *Tetrahymena* to assay for the biological agent and that is unclear how the introduction of *Tetrahymena* further limits the claim. Applicants notes that claims 17 and 29 recite "introducing *Tetrahymena pyriformis* to the sample". The addition of *Tetrahymena* to the sample bioencapsulates *Bacillus* spores, and hence concentrates and aids in the detection of *Bacillus* species (e.g. *Bacillus anthracis*).

Claims 32-36 stand rejected as indefinite. The Examiner states that claims 32, 34 and 35 require introducing the sample to a first or second membrane at a temperature effective to kill vegetative bacteria. The Examiner states that it is unclear how this results in identification of bacillus spores by addition of *Tetrahymena*.

Vegetative bacteria are also consumed by *Tetrahymena pyriformis*. Consumption of vegetative bacteria may dilute the concentration of *Bacillus* species within the *Tetrahymena pyriformis* and make detection more difficult (see page 16, lines 5-19).

In view of the remarks above, applicants request that the indefiniteness rejection be withdrawn.

#### **Rejections Under 35 U.S.C. § 102**

Claims 1-3, 11-16 and 22-27 stand rejected as anticipated by Cordery et al. (U.S. Pat. No. 6,613,571). Cordery discloses a mail receptacle for collecting air samples.

Claim 1 has been amended to recite that the sample domain is a route undertaken by a street sweeper machine. The Examiner states:

Incoming mail can be collected from mailboxes situated on public streets . . . therefore the mail is collected by Cordery et al. is from a route undertaken by a street sweeper machine . . .

Cordery does not expressly teach a sample domain that is "a route undertaken by a street sweeper machine". Also, the mere possibility that mail *may* be collected from a public street, which in turn *may* be in close proximity to a route undertaken by a street sweeper machine is not sufficient to inherently teach this limitation. See *Continental Can Co. v. Monsanto Co.*, 948 F.2d 1264, 1268 (Fed. Cir. 1991) (inherency cannot be established by probabilities or possibilities). There are many mail collection locations that do not include routes undertaken by a street sweeper machine (e.g. rural areas), and there are many areas in which street sweeper machines operate that are not served by the Postal Service (e.g. smaller or modified versions of street sweepers that are used within buildings).

Since Cordery does not disclose every limitation of claim 1, or claims 3-24 which depend therefrom, applicants request that this rejection be withdrawn.

Claims 25 and 26 call for a sample that "comprises debris or fluids that result from rising an instrumentality used in a collection of materials from a sample domain". The mail in Cordery is not rinsed. Accordingly, Cordery does not disclose this limitation and does not anticipate claims 25, 26 or claim 27 (which depends on claim 26).

Claims 1, 12-13, 15-17, 19-21, 29 and 31 stand rejected as anticipated by Manasherob (App. Envir. Microbio. 1998, 64:1750-1758). Manasherob discusses the bioencapsulation of *Bacillus thuringiensis* inside *Tetrahymena* protozoa. The fate of the *Bacillus thuringiensis* inside the food vacuoles was ascertained in a controlled experiment.

Claim 1 has been amended to recite that the sample domain is a route undertaken by a street sweeper machine. Claims 3-24 depend therefrom. Applicants request that the rejection of claims 12-13, 15-17, 19-21 be withdrawn.



Claim 25 has been amended to call for isolating a sample, which sample comprises debris or fluids that result from rinsing collection bins used to collect materials from a sample domain. Hoffmaster refers to eluting elution of swab specimens, but does not disclose or suggest a sample that includes debris or fluids that result from rinsing collection bins used to collect materials from a sample domain. While the vacuum cleaner in Hoffmaster is used to collect debris specifically for the Anthrax assay, there is no disclosure of rinsing a collection bin associated with the vacuum cleaner. Accordingly, Applicants request that the anticipation rejection of claim 25 over Hoffmaster be withdrawn.

Claim 26 recites a sample domain that includes a collection of materials on a regular, systematic basis through a predetermined, traceable route, the predetermined traceable route converging on a centralized location. As noted above, the collection of environmental samples in Hoffmaster was solely in response to an Anthrax outbreak. Hoffmaster does not teach or suggest the collection of materials on a regular, systematic basis nor does it disclose that the collection is through a predetermined, traceable route, the predetermined traceable route converging on a centralized location. Accordingly, applicants request that the anticipation rejection of claims 26-27 be withdrawn.

In view of the above amendments and remarks, applicants submit that this application is in condition for allowance. If there are any other issues remaining, which the Examiner believes could be resolved through either a Supplemental Response or an Examiner's Amendment, the Examiner is respectfully requested to contact the undersigned at the telephone number indicated below.

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Respectfully submitted,

By

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